APR 19 2011

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K110434

1. Date of Submission:
2010.12.21
2. Sponsor
Beijing Syntech Laser Co., Ltd.
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3. Submission Correspondent
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4. Proposed Device Identification

Proposed Device Name: Trixel CO_2 Laser/ Trixel II CO_2 Laser
Proposed Device Model: CFL-10/ UFL-60

Classification: 2
Product Code: GEX
Regulation Number: 21 CFR 878.4810
Review Panel: 878 General and Plastic Surgery

Intended Use Statement:
The equipment is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

5. US agent

U.S. Agent Contact Name WEI HUANG

U.S. Agent Business Name MID-LINK INTERNATIONAL, INC.

U.S. Agent Full Address 307 EAGLE HEIGHTS APT E, MADISON, WISCONSIN, 53705, UNITED STATES

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U.S. Agent Phone Number 608 -3355979

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6. Predicate Device Identification

510(k) Number: K101555

Product Name: CO_2 LASER SYSTEM

Manufacturer: ADVANCED TECHNOLOGY LASER CO., LTD.

7. Device Description

Trixel CO2 Laser is a carbon dioxide laser used in medical and aesthetic industry for treatment of such skin conditions as fine and coarse wrinkles, scars of various origin, uneven pigmentation and dilated pores. Due to the CO2 laser's high absorption of water, its high-energy beam of laser light interacts with the skin's surface causing the upper layer to peel off and use photothermolysis to stimulate deep cell regeneration and then achieve the target of skin improvement.

The equipment is mainly used for human tissue vaporization, carbonization, coagulation and exposure to achieve the purpose of treatment.

CFL-10 Trixel CO2 Laser:

The equipment includes the following:

One mainframe;

One footswitch;

One data cable;

One power wire;

One ventilation tube;

Six Wire clips;

Two keys;

One trixel (bitmap) scanner handpiece;

Two trixel laser position heads

One ordinary treatment handpiece with aimed light

A laser goggles;

Three 3.15A fuses;

One user manual.

UFL-60 Trixel II CO2 Laser:

The equipment includes the following:

One mainframe;

One set of footswitch;
One data cable;
One power wire;
One ventilation tube;
Six Wire clip;
Two keys;
One trixel (bitmap) scanner handpiece;
Three trixel laser position heads;
One ordinary treatment handpiece with aimed light
A laser goggles;
Three 5A fuses;
One user manual.

8. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification, requirements.
- IEC 60601-2-22: 2007, Medical Electrical Equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment – Part1: General requirements for safety.
- IEC60601-1-2:2001+A1:2004, Medical Electrical Equipment – Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.

9. Substantially Equivalent Conclusion

The proposed device, Trixel CO_2 Laser/Trixel II CO_2 Laser, has same Product Code, Regulation Number, Class, Maximum Power, Work Mode, Wavelength, Mode Structure, Spot Size, Pulse Setting, etc., but only different in five aspects as following:

1. Intended Use
2. Light Arm
3. Aiming Beam
4. Cooling System
5. Power Input

For these different, we have performed analysis as following:

Analysis 1: the intended use of predicate device includes the one of proposed device. They both have the function of vaporization and coagulation. The above clearance for intended use does not introduce any problems regarding the safety and effectiveness of the device.

Analysis 2: though the length of light arm is different, CFL-10: 0.97m, UFL-60: 1.17m, predicate device: 1.3m, it doesn't affect the treatment itself. This difference does not introduce any problems regarding the safety and effectiveness of the device.
See analysis 3: Both the output range of aiming beam is <5mW, which complies with the requirement of IEC 60601-2-22:2007. This difference does not introduce any problems regarding the safety and effectiveness of the device.

Analysis 4: air cooling system and water cooling system can both cool down the system. This difference does not introduce any problems regarding the safety and effectiveness of the device, they both comply with the requirement of IEC 60601-1.

Analysis 5: they have the similar power input, CFL-10 Trixel CO2 Laser: 120 V, UFL-60 Trixel II CO2 Laser: 120 V, predicate device: 115V. This difference does not introduce any problems regarding the safety and effectiveness of the device.

Basic on analysis above, proposed device has determined to be Substantially Equivalent (SE) to the predicate device, eBeam CO_2 Laser System (K101555), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 19 2011

Beijing Syntech Laser Co., Ltd
% Underwriters Laboratories, Inc.
Mr. Marc M. Mouser
2600 NW Lake Road
Camas, Washington 98607-9526

Re: K110434
Trade/Device Name: Trixel CO2 Laser/Trixel II CO2 Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 28, 2011
Received: April 4, 2011

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number: K110434

Device Name: Trixel CO2 Laser/Trixel II CO2 Laser

Indications for Use:

The equipment is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110434